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IN THE

Supreme Court of the United States

CROPLIFE AMERICA, *et al.*,
Petitioners,

v.

BAYKEEPER, *et al.*
Respondents.

AMERICAN FARM BUREAU FEDERATION, *et al.*,
Petitioners,

v.

BAYKEEPER, *et al.*
Respondents.

On Petitions for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

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BRIEF OF VALENT BIOSCIENCES CORPORATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE* [1]

Valent BioSciences Corporation ("VBC") manufactures a unique class of FIFRA-registered pesticides known as "biological pesticides," which consist of naturally occurring microorganisms. They are applied to water to control mosquito larvae before they grow into adults capable of transmitting disease; to the canopy of forests to control caterpillars that defoliate and destroy trees; and also to agricultural crops.

Biological pesticides are environmentally beneficial and play an important role in integrated pest and mosquito management programs. Their application to or near water, including the application of a subspecies of the naturally occurring soil bacterium *Bacillus thuringiensis* ("*Bt*"), does not produce biological wastes. Nor do biological pesticides alter the chemical, physical or biological integrity of the waters of the United States. The World Health Organization has concluded that "*Bt* products are unlikely to pose any hazard to humans or other vertebrates or to the great majority of non-target invertebrates. . . ."[2]

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[1] VBC states under Supreme Court Rule 37.6 that no counsel for a party authored this brief in whole or in part, and that no person or entity, other than VBC and its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Under Supreme Court Rule 37.2, on November 19 and 20, 2009, VBC provided counsel of record listed then on the Court docket with notice of its intention to file this brief. All of those parties have consented to the filing of the brief; their letters of consent are lodged with the Clerk.

[2] World Health Organization, *Bacillus Thuringiensis*, *Summary*, *available at* http://apps.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=16&codcch=217.

VBC devotes a substantial portion of its resources to the research and development, FIFRA registration, and commercialization of biological pesticides, including *Bt* larvicides. The industry that discovers and commercializes biological pesticides is comprised of many small or medium size businesses, such as VBC.

VBC respectfully submits that the Sixth Circuit's conclusion that a biological pesticide is always a Clean Water Act ("CWA") "pollutant" is wrong. *See* 33 U.S.C. § 1362(6). If allowed to stand, the lower court's decision will discourage, and in most cases prevent, the timely and effective use of biological pesticides, and also needlessly subject users of biological pesticides to CWA citizen suits. Losing the timely use of biological pesticides would be especially unfortunate because the CWA's goal is "to restore and maintain the chemical, physical and biological integrity" of waters, 33 U.S.C. § 1251(a), not to regulate as CWA pollutants environmentally beneficial biological pesticides, which help to protect public health and the natural environment.

VBC, which also submitted an *amicus curiae* brief below, is filing this brief in support of both certiorari petitions in order to urge the Court to review and correct the Sixth Circuit's decision, including specifically with respect to biological pesticides.

REASONS FOR GRANTING THE PETITIONS

Review should be granted in order to correct the lower court's erroneous holding that biological pesticides are CWA "pollutants." They are instead a unique and invaluable class of EPA-approved pesticides, comprised of naturally occurring microorganisms, including the soil bacterium *Bacillus thuringiensis* ("*Bt*"). *Bt* biological pesticides, also called *Bt* larvicides because they control insect larvae, are applied to water to control the larval form of the mosquito, an insect that causes more death and disease than any non-human animal. They also are applied to forests to control caterpillars that annually destroy millions of acres of trees. *Bt* larvicides not only are highly effective in controlling mosquito larvae and caterpillars, but also *benefit* the aquatic environment because they do not affect nontarget aquatic organisms. *Bt* biological pesticides provide significant net environmental, economic and public health benefits.

The CWA's illustrative "pollutant" example—"biological materials"—means biological *wastes*, not any and all material of a biological nature, such as *Bt* larvicides. And because they do not alter the integrity of the waters to which they are applied, *Bt* larvicides do not meet the CWA's definition of "pollution." Unless reversed, the Sixth Circuit's decision requiring compliance with time-consuming NPDES permit requirements will delay or prevent the timely and effective application of *Bt* biological pesticides to control disease-carrying mosquitoes and other target pests.

I. THIS CASE IS EXCEPTIONALLY IMPORTANT TO PUBLIC HEALTH AND THE PROTECTION OF FORESTS BECAUSE UNLESS THE SIXTH CIRCUIT'S DECISION IS REVERSED, THE AVAILABILITY AND EFFECTIVE USE OF STATE-OF-THE-ART, NATURALLY OCCURRING BIOLOGICAL PESTICIDES WILL BE SERIOUSLY CURTAILED, IF NOT COMPLETELY LOST

Bt biological pesticides benefit the environment while controlling insects. *Bt* larvicides are inherently less toxic to man and the environment than conventional chemical pesticides. In contrast with most conventional chemical pesticides, which may affect a large spectrum of organisms, including adversely affecting non-target organisms, *Bt* larvicides affect only the biology of the larva of a particular insect pest, and they decompose quickly in the water. Indeed, EPA has stated that "[e]xtensive testing shows that microbial [*i.e.*, biological] larvicides do not pose risks to wildlife, nontarget species, *or the environment*, when used according to label directions."[3] For these reasons, *Bt* biological pesticides provide significant net environmental, economic and social benefits. They protect public health. They also reduce forest defoliation and thereby maintain the capacity of forests to capture carbon and offset greenhouse gas emissions and control insects that jeopardize wildlife.

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[3] EPA, *Larvicides for Mosquito Control, available at* http://www.epa.gov/opp00001/health/mosquitoes/larvicides4mosquitoes.htm (hereinafter "EPA, *Larvicides for Mosquito Control*") (emphasis added).

The National Research Council, whose members are drawn from the Councils of the National Academy of Sciences, reported in 2000 that while conventional pesticides will continue to play an important role in pest control technology, there remains the need for pest controls that are consistent with ecologically-based pest management.[4] Biological pesticides are consistent with ecologically-based pest management. The Sixth Circuit's holding that biological pesticides are CWA "pollutants" will discourage their continued development and use. By subjecting these highly beneficial and time-sensitive products (which EPA has repeatedly determined are safer for the environment than conventional pesticides) to a lengthy permitting process, the Sixth Circuit decision will sharply curtail and reverse efforts to control harmful and life-threatening diseases and the adverse effects associated with deforestation.

A. The Sixth Circuit's Decision Vacating EPA's Final Rule and Requiring NPDES Permits for Biological Pesticides Will Frustrate If Not Altogether Prevent Their Timely and Effective Use

To initiate the process of complying with the lower court's decision, EPA, on October 7, 2009, released for comment draft conditions for applying pesticides under an National Pollutant Discharge Elimination System ("NPDES") pesticide general permit ("PGP").[5]

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[4] National Research Council, Committee on the Future Role of Pesticides in US Agriculture, *The Future Role of Pesticides in US Agriculture* (2000) at 251-52, *available at* http://books.nap.edu/openbook.php?record_id=9598&page=R1.

[5] EPA, *Clean Water Act Permitting of Discharges from Pesticide Applications* (Webinar) (Oct. 7, 2009), *available at* http://

In particular, under the draft conditions, applicators of all pesticides to or near water must hold, as of April 10, 2011, an individual NPDES permit or comply with the conditions of a PGP. The PGP will impose a myriad of conditions and restrictions on pesticide applicators, including the requirement to file a Notice of Intent ("NOI") before applying pesticides, technology and water quality-based effluent limits, and monitoring and reporting requirements. Governmental and private entities charged with controlling nuisance and disease-carrying mosquitoes face severe budgetary constraints in the current economy. They can ill afford the additional costs of complying with the conditions of PGP, especially when, in the case of biological pesticides, compliance will not bring any additional benefits to man or the environment.

The use of larvicides for mosquito control is widespread: they are applied to treat four million acres of water annually.[6] The application of *Bt* for larval control also is extremely time-sensitive. For mosquito control, *Bt* biological pesticides must be applied while the larvae are in their feeding stage and before they enter the pupae phase, a narrow and time critical window of several days. Moreover, mosquito larvae populations can increase as a result of unexpected rains and high tides.

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www.epa.gov/pesticides/ppdc/2009/october/session-1.pdf (hereinafter "EPA, *CWA Permitting of Discharges from Pesticide Applications*").

[6] EPA, NPDES Application Estimates and Information Sources (draft) (Sept. 23, 2009) *available at* http://www.epa.gov/pesticides/ppdc/2009/october/session1-npdes.pdf. (hereinafter "EPA NPDES Application Estimates").

The Sixth Circuit's decision will prevent the timely and effective application of *Bt* biological pesticides. EPA has stated that "[a] person filing an NOI would be covered starting 10 days *after* receipt of a complete and accurate NOI form by the appropriate permitting authority (provided the permitting authority does not delay authorization to further assess the NOI)."[7] Requiring applicators to wait ten days before using the *Bt* larvicides likely will force them to miss the critical larvae feeding stage. While pesticides may be applied in emergency situations before the submission of a NOI, the purpose of mosquito larviciding is to avoid an emergency. Because the Sixth Circuit decision will, as a practical matter, prevent the timely use of *Bt* larvicides, the decision will have a significant adverse impact on the use of these beneficial pest control products.

B. *Bt* Larvicides Are Critical for Effective Mosquito Control

The mosquito is a very efficient carrier of disease. It causes more human suffering and death than any non-human animal.[8] The mosquito transmits more than 100 pathogens that cause protozoan diseases such as malaria, filarial diseases such as heartworm, and viral diseases such as yellow fever, dengue fever, encephalitis, and West Nile virus. Each year there are 300 to 500 million cases of malaria reported worldwide, resulting in at least one million deaths

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[7] EPA, *CWA Permitting of Discharges from Pesticide Applications* (slide 45) (emphasis added).

[8] American Mosquito Control Association, *Mosquito-Borne Diseases, available at* http://www.mosquito.org/mosquito-information/mosquito-borne.aspx.

every year.[9] CDC already has reported 608 cases of mosquito-transmitted West Nile Virus, and 28 deaths, in 2009.[10]

All mosquitoes begin life in stagnant or standing water and develop through four stages of metamorphous: egg, larva, pupa, and adult. The female's eggs hatch within a day or two, releasing larvae that only live in water from four to fourteen days, after which they change to pupae before becoming adult mosquitoes that take flight. Public and private mosquito control programs practice Integrated Mosquito Management, which seeks to control mosquitoes by reducing aquatic breeding sites for the larvae. When monitoring and surveillance programs confirm the need to control mosquito larvae with pesticides, the FIFRA-registered choices include biological pesticides such as *Bt* larvicides, biochemical pesticides such as methoprene (an insect growth regulator), and conventional organophosphate chemical insecticides.[11] Unlike the more limited and precise application of larvicides, the control of adult mosquitoes requires the ground and aerial spraying of conventional organophosphate chemical pesticides over much larger areas.[12]

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[9] Centers for Disease Control and Prevention, *The Impact of Malaria, A Leading Cause of Death Worldwide, available at* http://www.cdc.gov/malaria/index.htm.

[10] Centers for Disease Control and Prevention, *West Nile Virus, Statistics, Surveillance, and Control, available at* http://www.cdc.gov/ncidod/dvbid/westnile/surv&controlCaseCount09_detailed.htm#MeningitisEnc.

[11] American Mosquito Control Association, *Control, available at* http://www.mosquito.org/mosquito-information/control.aspx.

[12] EPA, *Larvicides for Mosquito Control* ("Killing mosquito larvae before they emerge as adults can reduce or eliminate the

The most widely used biological pesticide applied to water to control mosquito larvae are two subspecies of *Bt*: *Bacillus thuringiensis israelensis* ("*Bti*") and *Bacillus sphaericus* ("*B. sphaericus*"). Mosquito larvae consume the dormant *Bt* bacterium spores and an associated *Bt* toxin that binds to receptor cells in the mosquito larva's gut, thereby causing the larva to starve. These receptor cells are not present in fish or mammals. *Bti* and *B. sphaericus* therefore benefit the environment because they control only the mosquito larvae and do not affect other nontarget aquatic organisms.[13] *Bt* biological pesticides serve as an important tool in managing the mosquito's development of resistance to traditional chemical larvicides and adulticides.[14]

C. *Bt* Larvicides Also Are Important for Protecting Forests

EPA's Final Rule, 71 Fed. Reg. 68,483 (Nov. 27, 2006), cited, as an example of pesticides that are applied "near" water, insecticides that are applied aerially to the forest canopy to control foliage-feeding caterpillars where waters of the United States may be present below the canopy. Pet. App. 7a. In 2008, the Gypsy Moth alone defoliated 1,593,649 acres of trees in the northeastern United States.[15] There are

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need for ground or aerial application of pesticides to kill adult mosquitoes.").

[13] *Id.*

[14] North Carolina State University, *Pesticide Resistance Management, available at* http://ipm.ncsu.edu/apple/orchardguide/Resistance.pdf.

[15] USDA, Forest Service, *Northeastern Area, Gypsy Moth Digest—Defoliation, available at* http://na.fs.fed.us/fhp/gm/defoliation/index.shtm.

2.7 million acres of forests that are treated every year to control caterpillars.[16] The Sixth Circuit's decision will also preclude the timely and effective use of these biological pesticides to control caterpillars that kill trees. Preserving forests through the application of biological pesticides contributes to clean water because forests serve to filter pollutants.[17]

Commercial formulations of *Bacillus thuringiensis* subspecies ***kurstaki*** (***"Btk"***) have been used to control forest caterpillar pests since the mid-1970's. More than a million pounds of ***Btk*** are applied annually in the United States to control the destructive gypsy moth. A total of 2,743,816 acres were treated with ***Btk*** formulations between 1995 and 2002.[18] As with other subspecies of ***Bt***, ***Btk*** is considered "friendly" to humans and the environment. It controls only susceptible caterpillars by the mechanism described above. "U.S. EPA (1998) classifies ***Btk*** as virtually non-toxic to fish, based on an assessment of several acute toxicity studies in trout and one study in bluegills."[19]

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[16] EPA NPDES Application Estimates.

[17] CNN, *Study: Saving Forests Best Way To Cheap, Clean Water, available at* http://www.cnn.com/2003/TECH/science/09/03/forests.water.reut/index.html.

[18] USDA, Forest Service, *Control/Eradication Agents for the Gypsy Moth Human Health and Ecological Risk Assessment for Bacillus thuringiensis var. kurstaki (B.t.k.), available at* http://www.fs.fed.us/foresthealth/pesticide/pdfs/060804_btk.pdf.

[19] *Id.* at 4-8.

D. EPA Has Recognized That Biological Pesticides Pose Lower Risks Than Most Conventional Pesticides

EPA is responsible for registration of the following categories of pesticides under FIFRA: conventional (chemical) pesticides, biological pesticides (or microbials or biopesticides), biochemical pesticides, plant-incorporated protectants (plants that genetically produce their own pesticides), and antimicrobial pesticides (*e.g.*, disinfectants). *See* 72 Fed. Reg. 60,988, 60,989 (Oct. 26, 2007). The Agency has stated that "[t]hese pesticides, although regulated under the same statutory standards under FIFRA and FFDCA, pose different levels of risk and exposure. . . ." *Id.*

Because they consist of naturally occurring microorganisms, EPA has stated that "[b]iopesticides are usually inherently less toxic than conventional pesticides."[20] The Agency requires all pesticide applicants to submit toxicology and environmental studies, which the Agency reviews to determine whether a pesticide meets FIFRA's "no unreasonable adverse effects on the environment" standard for registration. *See* 7 U.S.C. § 136a(c)(5)(D). But because biological pesticides are inherently less toxic than conventional pesticides, EPA requires applicants for biological pesticide registrations to submit much less data than applicants seeking to register conventional pesticides. *Compare* 40 C.F.R. §§ 158.1—158.1410 (data requirements for conventional pesticides) *with* 40 C.F.R. §§ 158.2100—158.2174 (data requirements for microbial pesticides).

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[20] EPA, *What Are Biopesticides?*, *available at* http://www.epa.gov/pesticides/biopesticides/whatarebiopesticides.htm. (hereinafter "EPA, *What are Biopesticides?*").

In 1995, EPA created the Biopesticides and Pollution Prevention Division to bring "safer pesticides products into the market place and to encourage the adoption of these safer, reduced risk products and related integrated pest management (IPM) practices."[21] EPA Guidelines for expedited review of conventional and biological pesticides explain that "EPA believes that biological pesticides generally pose less risk than most conventional pesticides."[22]

The Sixth Circuit's decision would require all users of these beneficial and efficacious biological pesticides to submit to the time-consuming NPDES permitting process, which will hamper, if not largely prevent, the use of these products to control disease and deforestation.

II. THE SIXTH CIRCUIT'S DECISION IS PREMISED IN PART ON FUNDAMENTAL ERRORS REGARDING BIOLOGICAL PESTICIDES

A. Biopesticides Are Not "Biological Material" Pollutants Under the Clean Water Act

Biological pesticides are not CWA pollutants because they are not biological *wastes*. The Sixth Circuit's decision that biological pesticides, which benefit public health and the environment, are CWA pollutants because they may superficially "fit into the ordinary meaning of 'biological materials,'" Pet. App.

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[21] Russell S. Jones, *The Biochemical Classification Committee and the Classification of Biochemical Active Ingredients, available at* http://www.pharmsolutions.com/docs/ClassificationBioChemicalActiveIngredients.htm.

[22] EPA, Pesticide Registration Notice 97-3 at XI(B), *available at* http://epa.gov/PR_Notices/pr97-3.html.

19a, is wrong. That conclusion produces absurd results and is at odds with basic principles of statutory construction and established case law holding that "biological materials" means biological *wastes*.

The Sixth Circuit cited no legislative history remotely suggesting that when Congress passed the CWA in 1972, it intended that any and all "matter of a biological nature" introduced into the waters of the United States would constitute the prohibited discharge of a pollutant. Pet. App. 21a. If that were true, then Congress intended that the state game warden who stocks the local trout stream in the Spring with "artificial concentrations" of young trout, or the fisherman who casts upon the waters the sacrificial worm, must first obtain a NPDES permit. Under the Sixth Circuit's decision, both the trout and the worm would squarely qualify as "biological materials" within the "ordinary, contemporary, [and] common meaning" of the term, thus requiring an NPDES permit. *See id.* at 20a-21a, citing *Grand Traverse Band of Ottawa & Chippewa Indians v. Office of U.S. Attorney*, 369 F.3d 960, 967 (6th Cir. 2004).

"Biological materials" as used in the CWA definition of "pollutants," however, means biological *wastes*. *Bt* larvicides are not biological wastes. They are applied to or near waters of the United States to protect the environment, public health and natural forestry resources. After serving their intended beneficial purpose they do *not* leave a residue or waste in the waters because they consist of naturally occurring bacteria.[23]

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[23] EPA Pesticides Glossary, *available at* http://www.epa.gov/pesticides/glossary/#b (hereinafter "EPA Pesticides Glossary").

The "precise question at issue" is whether, when Congress enacted the CWA in 1972, it clearly intended that a "biological pesticide" applied to water to control a pest was a prohibited "pollutant." *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 837-38 (1984). The Sixth Circuit committed clear error when, instead of ascertaining "whether Congress has directly spoken to the precise question at issue," it quoted two dictionary definitions of "material" and summarily declared that the "plain, unambiguous nature of" biological materials compels the conclusion that biological pesticides are CWA pollutants. Pet. App 20a-21a. *Chevron* requires more.

A court must assess the clarity or lack of clarity of statutory language by employing all of the traditional tools of statutory construction. *Chevron*, 467 U.S. at 843, n.9 ("If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect."). Thus, the clarity or ambiguity of the statutory term "biological materials" must not be assessed in a vacuum, or merely by reference to general dictionary definitions, but instead must be assessed within the context of whether Congress intended "biological materials" to encompass beneficial biological pesticides. *See generally Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 666 (2007) ("[T]he meaning—or ambiguity—of certain words or phrases may only become evident when placed in context. . . . It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132-33 (2000)) (internal

quotation marks omitted); *Zuni Pub. School Dist. No. 89 v. Dep't of Educ.*, 550 U.S. 81, 98 (2007) (statutory "[a]mbiguity is a creature not [just] of definitional possibilities but [also] of statutory context.") (quoting *Brown v. Gardner*, 513 U.S. 115, 118 (1994)).

The context of the CWA demonstrates that Congress did not intend "biological materials" to include biological pesticides. EPA did not register the first *aquatic Bt* biological larvicide, *Bti*, for the control of mosquito larvae until 1983. It did not register the second *Bt* mosquito larvicide, *B. sphaericus*, until 1991.[24] As EPA's Final Rule noted, "[t]he fact that more biological pesticides have been developed since passage of the [Clean Water] Act in 1972 does not justify expanding the reach of the NPDES permit requirement when there is no evidence that Congress intended the CWA to regulate biological pesticides in a manner different from chemical pesticides." Final Rule, 71 Fed. Reg. at 68,486. Because Congress could not have directly addressed whether "biological materials" includes "biological pesticides," the Sixth Circuit should have afforded *Chevron* deference to EPA's Final Rule, which concluded that "it would not make sense, and would be inconsistent with the goals of the Clean Water Act, to discourage the use of biological pesticides by requiring applicators of these products to obtain an NPDES permit when chemical pesticides have no such requirement." *Id.* at 68,486-87.

Ironically, to bolster its conclusion that "biological materials" includes biological pesticides, the Sixth Circuit looked at an EPA definition of the term "biological pesticides." Pet. App. 22a-23a. The Sixth

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[24] EPA, *Larvicides for Mosquito Control*.

Circuit, however, materially misstated EPA's definition. According to the Sixth Circuit, EPA defines "biological pesticides" to include "other biological materials." *Id.* In fact, the EPA definition of "biological pesticides" does *not* include "other biological materials," but only "certain microorganisms, including bacteria, fungi, viruses, and protozoa that are effective in controlling target pests."[25]

The Sixth Circuit also erred when it assumed that biological pesticides are wastes. *Bt* biological pesticides are not wastes: they leave no residue in the water after serving their intended purpose of controlling mosquito larva.[26] Courts treat "biological materials" as pollutants only if they are biological wastes.

In each of the "biological materials" cases cited by the Sixth Circuit, the court specifically found that human activity generated a biological waste. For example, in *Association to Protect Hammersley, Eld, & Totten Inlets v. Taylor Resources, Inc.*, 299 F.3d 1007, 1016 (9th Cir. 2002), the Ninth Circuit found the CWA to be "ambiguous on whether 'biological materials' means *all* biological matter regardless of quantum and nature." The court held that mussel shells, mussel feces, and other biological materials emitted from mussel-harvesting facilities were not "biological materials" because "the shells and natural byproduct of living mussels released . . . are the result of the natural biological processes of the mussels, *not the waste product of* a transforming human process." *Id.* at 1017 (emphasis added). Applying the doctrine of *ejusdem generis*, the court found that the "more specific items in the illustrative

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[25] EPA Pesticides Glossary.

[26] *Id.*

list of pollutants . . . support an understanding of the more general statutory term, 'biological materials,' as *waste* material of a human or industrial process." *Id.* at 1016 (emphasis added).

In the second case cited by the Sixth Circuit, *National Wildlife Federation v. Consumers Power Co.*, 862 F.2d 580 (6th Cir. 1988), the court found that fish *remains* discharged from a hydroelectric facility are pollutants since they are "biological materials." That the biological materials—dead fish and fish parts—remain in the water after the human activity attests to their characterization as "biological materials" *wastes*. In the third case, relied upon but not analyzed by the Sixth Circuit, *United States Public Interest Research Group v. Atlantic Salmon of Maine*, 215 F. Supp. 2d 239 (D. Me. 2002), the district court went no further than to hold that non-North American salmon that escape from an aquaculture facility are "biological materials" because the fish do not occur naturally in that water and that salmon feces and urine that escape the facility's nets are either "biological materials" or "agricultural wastes." *Id.* at 247-49. Animal feces and urine are biological materials, but more importantly they are wastes—the useless byproducts of metabolism.

Other courts have confirmed that biological materials means biological wastes. *See, e.g., Concerned Area Residents for the Env't v. Southview Farm*, 34 F.3d 114, 117 (2d Cir. 1994) (liquid manure spread on farm fields met definition of pollutant as it was "solid waste, . . . sewage, . . . biological materials, . . . and agricultural waste discharged into water"); *United States v. Plaza Health Laboratories, Inc.*, 3 F.3d 643, 645 (2d Cir. 1993), *cert. denied*, 512 U.S. 1245 (1994) (discarded vials of human blood are "biological mate-

rials"); *United States v. Frezzo Bros.*, 461 F. Supp. 266, 269-70 (E.D. Pa. 1978), *aff'd*, 602 F.2d 1123 (3d Cir. 1979) (runoff from pile of "mushroom compost" was discharge of "sewage" and "biological materials").

EPA's Final Rule relied upon and cited most of these cases for the Agency's well supported conclusion that "[i]n cases in which courts have found specific biological materials to be 'pollutants' under section 502(6) the substances at issue were waste materials discharged from a point source." 71 Fed. Reg. at 68,487. The Sixth Circuit found a conventional pesticide to be a "chemical waste" only if it leaves an excess portion in the water "after performing its intended purpose." Pet. App. 18a. For this reason, a *Bt* bacterium is a biological waste only when it too leaves an excess portion in the water after performing its intended purpose. But because they are naturally occurring, *Bt* bacterium do not leave an excess portion in the water after performing their intended purpose. Therefore, *Bt* larvicides are not pollutants under the Clean Water Act.

B. Biopesticides Do Not "Undeniably Alter the Physical Integrity of the Waters"

After mistakenly concluding that biological pesticides are CWA "pollutants" because they fit within the ordinary meaning of "biological materials," the Sixth Circuit then mistakenly concluded that a biological pesticide must meet the CWA's definition of "pollution," 33 U.S.C. § 1362(19), because, when added to water, they "undeniably alter its biological integrity." Pet. App. 23a. There is no evidence even remotely suggesting, however, that the addition of naturally occurring *Bt* biological pesticides alters the biological integrity of the waters of the United States.

Instead, EPA has concluded that biological pesticides do not alter the water integrity. The Agency defines "biological integrity" of water as "the capability of supporting and maintaining a balanced, integrated, adaptive community of organisms having a species composition, diversity, and functional organization comparable to that of the natural habitat of the region."[27] The application of *Bti* and *B. sphaericus* to aquatic environments to control mosquito larvae, as well as the application of *Btk* near water to control caterpillars that defoliate trees, meet EPA's criteria for preserving the water's biological integrity. Because they are naturally occurring, they degrade quickly.[28] EPA has expressly stated that "[e]xtensive testing shows that microbial larvicides *do not pose risks to wildlife, nontarget species, or the environment*, when used according to label directions."[29] Similarly, EPA has classified *Btk* as nontoxic to fish and aquatic invertebrate. Because EPA has determined that biological pesticides do not pose risks to nontarget aquatic species, the Sixth Circuit erred when it concluded that it is "undeniable" that biological pesticides alter the biological integrity of waters of the United States.

The Sixth Circuit incorrectly concluded that the CWA's definitions of "pollutant" and "pollution" are unambiguous and include biological pesticides. In so doing, the court unnecessarily subjected users of beneficial biological pesticides to a costly and time-

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[27] EPA, *Biological Integrity*, *available at* http://www.epa.gov/bioiweb1/html/biointeg.html.

[28] EPA, *What are Biopesticides?* ("Biopesticides . . . often decompose quickly . . .").

[29] EPA, *Larvicides for Mosquito Control*. (Emphasis added.)

consuming NPDES permitting process that will hinder the timely use of these products for important public health and environmental uses.

CONCLUSION

The petitions for a writ of certiorari should be granted.

Respectfully submitted,

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